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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,233	10/31/2003	Scott C. Mayer	16156-040001	3370
26169	7590	11/28/2005	EXAMINER	
FISH & RICHARDSON P.C. P.O BOX 1022 MINNEAPOLIS, MN 55440-1022			MAIER, LEIGH C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,233

Applicant(s)

MAYER ET AL.

Examiner

Leigh C. Maier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 4-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/31/03</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Claims

The instant application is a divisional of S.N. 09/449,003 which presented original claims 1-8. Claims 4-7 are pending in the present application, and the pre-amendment, submitted 10/31/03, indicates that claims 1-3 and 9 are canceled. It appears that what is intended is that claims 1-3 and 8 are canceled, as the examiner finds no claim 9 to be canceled or a claim 8 in the list of claims. This action is based on what appear to be the only pending claims, 4-7.

Claim Rejections - 35 USC § 112 – 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-6 recite methods of treating or inhibiting proliferative disorders. Typically “inhibition” is used regarding processes, such as the underlying mechanism causing a disorder, and “prevention” or “prophylactic treatment” is used regarding the disorder or disease, *per se*. In these claims, it would appear that “inhibiting” is used to mean “preventing.”

Claims 4 and 5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for prevention of hyperproliferative vascular disorders (such as restenosis), does not reasonably provide enablement for prevention of such disorders in the general population. The specification does not enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- (1) The quantity of experimentation necessary (time and expense);
- (2) The amount of direction or guidance presented;
- (3) The presence or absence of working examples of the invention;
- (4) The nature of the invention;
- (5) The state of the prior art;
- (6) The relative skill of those in the art;
- (7) The predictability or unpredictability of the art; and
- (8) The breadth of the claims.

The claims are drawn to methods including the prevention of hyperproliferative vascular disorders in a mammal "in need thereof." The specification discusses a population (surgical patients) that would be in need of prevention, but Applicant does not appear to contemplate that the claims be limited to this population. Otherwise, claim 6 would not be limiting. However, the specification does not describe how patients in need would be identified. While prophylactic treatment of surgical patients (with other therapeutic agents) is well known in the art, general prophylactic treatment is not well known. The specification does not present any working example that would provide guidance for prophylactic treatment of any subjects in need other than surgical patients. Therefore, one of ordinary skill would require undue experimentation, expending time and monetary resources to use this invention commensurate with the scope recited in the claims.

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Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to the administration of the recited compounds for the inhibition of angiogenesis in various cancers. However, there is no indication that any of the compounds have anti-angiogenic activity. The only *in vitro* assay provided demonstrates the inhibition of proliferation of smooth muscle cells (SMCs), but this is not the accepted assay for angiogenic activity. As Applicant admits, agents such as heparin also inhibits proliferation of SMCs but promotes epithelial cell growth. See the paragraph bridging pages 1 and 2 of the instant specification. It is the inhibition (or growth promotion) of epithelial cell tissue that is the accepted model for determining anti-angiogenic (or angiogenic) activity. See, for example, HUGHES (Exp. Cell Res., 1996).

Although the level of skill in this art would be expected to be high, the level of predictability regarding the activities of various compounds is low. The claims are drawn to lactobionamides, similar in structure to oligosaccharides. However, some oligosaccharides are known to be useful for the promotion of wound healing because they are angiogenic. See MICHAELI (US 4,912,093) and McCLUER et al (US 4,895,838). On the other hand, PARISH et al (US 6,143,730) discloses activities of heparin and various oligosaccharides. Some have anti-angiogenic activity, and some do not. See, for example, Table 1.

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In view of the foregoing, it appears that one of ordinary skill would require undue experimentation to determine which, if any, of the recited compounds would be useful for the inhibition of angiogenesis as set forth in the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over NGUYEN et al (WO 96/14325).

The claims are drawn to the treatment and prevention of vascular disorders comprising administering benzylmaltosides.

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NGUYEN teaches the administration of benzylglucosides and maltosides for the treatment of vascular disorders, such as restenosis, which are characterized by excessive smooth muscle cell (SMC) proliferation. See abstract. The reference does not exemplify administration of these compounds to a mammal. However, the reference tabulates data regarding SMC antiproliferation activity of several compounds which are encompassed by the instant genus. Compounds include examples 3, 4, 6, 8 and 29. See Table I at page 15.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to select any of the compounds described by NGUYEN having SMC antiproliferation activity for the treatment of vascular disorders, such as restenosis. One of ordinary skill would reasonably expect success with such treatment because the reference expressly suggests the compounds' use in such a manner.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim because the examined application claim is either anticipated by, or would have been obvious over, the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Claims 4-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 37 of U.S. Patent No. 5,773,420. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Reference claim 37 is drawn to the treatment of restenosis comprising the administration of a compound from the genus recited in claim 36, from which it depends. In describing the invention, the specification discloses several species that are encompassed by the instant genus and have the SMC antiproliferation activity necessary for the treatment of restenosis. It would be obvious to select any of these disclosed species in order to practice the invention as recited in reference claim 37. Therefore, this claim is not patentably distinct from instant claims 4-6.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov> Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Patent Examiner
November 22, 2005